FDA expands approval of closed-looped insulin delivery system

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(HealthDay)—Approval of the MiniMed 670G hybrid closed looped

system for diabetes management has been expanded to include individuals aged 7 to 13 years with type 1 diabetes, according to a report published by the U.S. Food and Drug Administration (FDA).

The MiniMed 670G hybrid closed looped system was originally approved in September 2017 for use in patients age 14 years and older with type 1 diabetes. The device works by measuring glucose levels in the body every five minutes and automatically adjusting insulin delivery. The system includes a sensor that measures glucose levels under the skin, an insulin pump, and an infusion patch connected to the pump. Users need to manually request insulin doses to counter carbohydrate consumption.

The FDA evaluated data from a clinical trial of the system in 105 individuals aged 7 to 11 years. Participants wore the device for about 3.5 months, and three phases of the study assessed home and remote use. No serious adverse events were recorded in association with use of the device, which was considered safe for people aged 7 to 13 years with type 1 diabetes.

"Today we're extending these opportunities to younger children who are especially vulnerable to the impact of this disease, such as the disruptions in sleep that can be caused by the need for frequent blood glucose checks," FDA Commissioner Scott Gottlieb, M.D., said in a statement.

More information: More Information